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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,772	06/29/2001	Keith D. Allen	R-268	9809
7590		11/19/2003	EXAMINER	
DELTAGEN, INC.		QIAN, CELINE X		
1003 Hamilton Avenue		ART UNIT		
Menlo Park, CA 94025		PAPER NUMBER		
		1636		

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/897,772	Applicant(s) ALLEN, KEITH D.	
	Examiner Celine X Qian	Art Unit 1636	

-- Th MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-16 and 23-36 is/are pending in the application.
 4a) Of the above claim(s) 13-16 and 23-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-36 is/are rejected.
- 7) ☒ Claim(s) 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 13-16 and 23-36 are pending in the application. Claims 13-16 and 23-27 are withdrawn from consideration for being directed to non-elected subject matter. Claims 28-36 are currently under examination.

This Office Action is in response to the amendment filed on 8/25/03.

Response to Amendment

The rejection of claims 1-12 and 17-22 under 35 U.S.C. 112 1st paragraph is moot in light of Applicant's cancellation of the claims.

The rejection of claims 1-4, 9, 10 and 19 under 35 U.S.C. 112 2nd paragraph is moot in light of Applicant's cancellation of the claims.

The rejection of claims 1-10 under 35 U.S.C. 102 (b) is moot in light of Applicant's cancellation of the claims.

The newly added claim 30 is objected to for following reasons.

The newly added claims 28-36 are rejected under 35 U.S.C. 112 1st paragraph for reasons discussed below.

The newly added claims 28-36 are rejected under 35 U.S.C. 112 2nd paragraph for reasons discussed below.

The newly added claims 33-36 are rejected under 35 U.S.C. 102(b) for reasons discussed below.

Response to Arguments

Claim Objections

Claim 32 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 30. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is set forth by 35 U.S.C. 112, first paragraph which states that the: “*specification* shall contain a written description of the invention. . . [emphasis added].” The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that “as of the filing date sought, [the inventor] was in possession of the invention.” See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in “possession” of

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the invention claimed by describing the invention with all of its claimed limitations “by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The claims encompass a target construct, a cell or a transgenic mouse comprising a disruption of “a BMP gene.” BMP is a family of genes that are involved in bone differentiation which include BMP2-7. The specification only discloses the disruption of a BMP gene represented by SEQ ID NO:1 in a mouse and targeting constructs made by using the nucleic acid sequence of SEQ ID NO:1. The specification discloses that homozygous disruption of this gene result in mice with kinky tail, low body weight or short body length. The specification fails to disclose targeting constructs of other BMP gene or transgenic mouse has disruption in other BMP gene. It is unclear whether disruption of other BMP genes in mice would result in the disclosed phenotype. The structural functional relationship between gene disruption and disclosed phenotype is missing. As such, the specification neither describes the invention by its complete structure nor other identifying characteristics. Therefore, the specification fails to describe the invention in such a way to reasonably convey one skilled in the art that the inventors had possession of the invention at the time the application is filed.

Claim 29 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a cell isolated from the transgenic mouse which lacks expression of the BMP protein, does not reasonably provide enablement for a tissue obtained from the transgenic mouse. The specification does not enable any person skilled in the art to which it pertains, or

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with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The nature of the invention is a cell or tissue obtained from the transgenic mouse whose genome comprises a disruption in the endogenous BMP gene, wherein the transgenic mouse exhibits the phenotype of kinky tail, low body weight or short body length when the disruption is homozygous.

The specification teaches that the transgenic mouse comprising homozygous disruption of the endogenous BMP gene can be used as a disease model or screening for agents that ameliorate the phenotype caused by the gene disruption. The specification also teach a cell lacks production of the BMP protein can be used as an *in vitro* system to screening compounds that act to ameliorate disease symptoms. However, the specification does not teach how to use a tissue isolated from the transgenic mouse comprising a disruption of the BMP gene. The phenotype of the homozygous transgenic mouse comprising a disrupted BMP gene is kinky tail, short body length or low body weight, none of which can be observed in a tissue. In addition, the transgenic mouse of claim 8 also encompasses heterozygous mouse, whether the tissue obtained from such heterozygote would exhibit any phenotype is unpredictable. The breadth of the scope thus surpasses that is enabled by the teaching of the instant specification. As such, one of skilled in the art would have to engage in undue experimentation to use the invention in commensurate with the scope of the claim. Therefore, the claim is only enabled for a cell isolated from the transgenic mouse of claim 28 wherein the cell lacks production of the BMP protein.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 28-36, the recitation of “exhibits at least one of a kinky tail...” renders the claims indefinite because the exact meaning of the sentence is unclear. It appears that the mouse has multiple tail and at least one of it is kinky. Applicant is suggested to amend the claims to “exhibits at least one of the following phenotype: a kinky tail...”

Regarding claim 30, the recitation of “wherein the disruption in a homozygous state inhibits production of” renders the claim indefinite because the homozygous disruption does not inhibit the production of functional BMP, but results in the lack of production of functional BMP protein.

Regarding claims 31 and 32, the recitation of “wherein the pseudopregnant mouse gives birth to a chimeric mouse” renders the claims indefinite because a pseudopregnant mouse cannot give birth to any mouse. Applicant is suggested to amend the claim to “wherein said mouse gives birth to a chimeric mouse.”

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 33-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Luo et al (Genes & Development, 1995, Vol 9, pages 2808-2820).

Luo et al. disclose a BMP-7 knockout mouse (see page 2810, 1st col., 2nd paragraph). Luo et al. also disclose a method of making said mouse use embryonic stem cell technology (see abstract and page 2809, 2nd col., 2nd paragraph). Luo et al. also disclose the targeting constructs for BMP-7 gene (see Figure 1) and method of making said constructs. Luo et al. further disclose cells isolated from said mouse (see Figure 2). Claims 33-36 are drawn to a BMP targeting construct, methods of making said construct and a murine embryonic stem cell comprising a disruption of the BMP gene. The recitation of "wherein the construct when introduced into a murine...exhibits at least one of a kinky tail" is intended use for the construct which does not carry patentable weight. Therefore, Luo et al. disclose the instantly claimed invention.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

This application contains claims 13-16, 23-27 drawn to an invention nonelected with traverse in Amendment filed on 1/17/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
SENIOR EXAMINER